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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,505	04/06/2001	Eyal Raz	UCAL-203	6822

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EXAMINER

NGUYEN, QUANG

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,505

Applicant(s)

RAZ ET AL.

Examiner

Quang Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-32 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

- I. Claims 1-7, 10-16 and 19-32, drawn to a polynucleotide vaccine comprising a nucleic acid sequence encoding an allergen modified by deletion of a native signal sequence; and methods for modulating an immune response to the antigen or for eliciting an immune response to the antigen, classified in class 514, subclass 44.
- II. Claims 1-5, 8-11, 15-21, 26-29 and 31-32, drawn to a polynucleotide vaccine comprising a nucleic acid sequence encoding a pathogenic antigen modified by deletion of a native signal sequence; and methods for modulating an immune response to the antigen or for eliciting an immune response to the antigen, classified in class 514, subclass 44.

Claims 1-5, 10-11, 15-16, 19-21, 26-29 and 31-32 link a plurality of above patentably distinct groups of encoded allergen and pathogenic antigen that lack the unity of invention because they do not share a substantial common core structure or element among themselves. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial

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structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect an encoded antigen as an allergen or a pathogenic antigen.

Should Applicants elect Group I, further group restriction is required because claims 1, 10 and 12 link a plurality of patentably distinct groups of encoded allergen comprising: plant allergen; food allergen; latex allergen; cat dander allergen; cockroach allergen; and house dust mite allergen that lack the unity of invention because they do not share a substantial common core structure or element among themselves. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect a specific allergen cited above.

Should Applicants elect Group II, further group restriction is required because claims 1, 8, 9, 15, 17 and 18 link a plurality of patentably distinct groups of encoded pathogenic antigen comprising: bacterial antigen; viral antigen and parasitic antigen that lack the unity of invention because they do not share a substantial common core structure or element among themselves. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect a specific pathogenic antigen cited above.

The restriction requirement between linked inventions is subject to the non-allowance of the linking claims 1-5, 10-11, 15-16, 19-21, 26-29 and 31-32. The

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restriction requirement between linked inventions is subject to the non-allowance of the linking claim(s), 1-5, 10-11, 15-16, 19-21, 26-29 and 31-32.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-II are distinct each from the others as they are drawn to distinct polynucleotide vaccines containing nucleic acid sequences encoding antigens (e.g., allergens and pathogenic antigens) that do not share a substantial common core structure or element among the antigens. Additionally, depending on the nature of the encoded antigen whether the antigen is an allergen or a pathogenic antigen, modulating or eliciting specific immune responses to the antigen is desired and contemplated by Applicants. For example, suppression of the IgE production

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against an allergen is desired or contemplated by Applicants, whereas this suppression is not required in the situation of a pathogenic antigen.

Because these inventions are distinct for the reasons set forth above, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single patent application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect Group I; and plant allergen as a separate group, claims 1, 10 and 12-14 are generic to a plurality of disclosed patentably distinct species comprising: (i) ragweed; and (ii) grass pollen.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, Should Applicants elect either Group I or II, claims 1, 11, 19-21, 26, 32 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named sequence listed in the Markush group of claim 21 or claim 32.

Applicant is also required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.



DAVE T. NGUYEN
PRIMARY EXAMINER